| NIDA-CTN- | Protocol Title: | |
|---|---|---|
| Node ID & Name: | Site ID & Name: | Visit Date(s): |
| Node Principal Investigator (PI): | | |
| Node Protocol PI: | Site Monitor: | |
| Site PI: | Node Protocol Coordinator: | |

Study Type: ☐ Behavioral ☐ Medication ☐ Combination ☐ Other

| Site Visit Attendees: |
|---|

1. Study Site Address

_____

2. Name of Site Study Coordinator

_____

| Complete the following checklist indicating one of the following choices for each item: | |
|---|---|
| **Yes** | In the opinion of the QA monitor, all versions of the specified documents, all supplies, all procedures* are present and up-to-date |
| **No** | In the opinion of the QA monitor the documents, supplies, or procedures* are not sufficient for site initiation. If No, provide explanation in the comments section along with any action to be taken. Also, include these issues in Section XI. Issues Identified. Please note: Many issues identified during this visit may be resolved during the visit with further discussion and/or instructions, and would not, therefore, be checked "No". |
| **N/A** | Not Applicable - *this is based on study instructions and will be pre-defined per protocol* |
| **N/R** | Not Reviewed – *provide explanation in the comments section and indicate when review will be performed* |
| *Please note that the examples included do not constitute an exhaustive list. | |

| **I. Review of Regulatory Files:** Use the Table of Contents from "RAS Regulatory Tabs Document (RAS 004, version 8C, or current version)," as a checklist reference. See addendum to this report form. | **Yes** | **No** | **N/A** | **N/R** |
|---|---|---|---|---|
| A. Using the most recent version of the RAS Regulatory Files Document guidelines, are the Regulatory Files complete and up-to-date? | ☐ | ☐ | ☐ | ☐ |
| **Comments** (Identify documents which are not complete, missing, and/or not up-to-date): | | | | |

| **II. Site/Other** | **Yes** | **No** | **N/A** | **N/R** |
|---|---|---|---|---|
| A. Are study site facilities suitable? | ☐ | ☐ | | ☐ |
| B. Are all study equipment and non-medication supplies vital to the conduct of the protocol available? | | | | |
| 1. Urine collection cups | ☐ | ☐ | ☐ | ☐ |
| 2. Drug and Alcohol test strips | ☐ | ☐ | ☐ | ☐ |
| 3. ECG equipment | ☐ | ☐ | ☐ | ☐ |
| 4. Blood draw supplies | ☐ | ☐ | ☐ | ☐ |
| 5. Centrifuge | ☐ | ☐ | ☐ | ☐ |
| 6. Refrigeration | ☐ | ☐ | ☐ | ☐ |
| 7. Audio and video tapes and supplies | ☐ | ☐ | ☐ | ☐ |
| 8. Equipment calibration logs | ☐ | ☐ | ☐ | ☐ |
| 9. Other: _____ | ☐ | ☐ | ☐ | ☐ |
| C. Are study supplies and equipment listed above properly stored in a secured area? | ☐ | ☐ | ☐ | ☐ |
| D. Is condition of study equipment/supplies (other than drug) appropriate for use (e.g., expiration date, condition, storage requirements, temp.), per manufacturer's instructions? | ☐ | ☐ | ☐ | ☐ |
| E. Are plans in place for proper monitoring of equipment and supplies, per manufacturer's instructions? | ☐ | ☐ | ☐ | ☐ |
| F. Are procedures for reordering and final destruction of supplies (other than drug), if applicable, understood? | ☐ | ☐ | ☐ | ☐ |
| G. Are blinded randomization envelopes, materials, and/or procedures in place, per protocol? | ☐ | ☐ | ☐ | ☐ |

| **II. Site/Other** | **Yes** | **No** | **N/A** | **N/R** |
|---|---|---|---|---|
| 8. Are local SOPs developed for clinic procedures as they relate to the protocol, on file, and understood by study staff regarding the following: | | | | |
| 1. Facility Emergency plan | ☐ | ☐ | ☐ | ☐ |
| 2. Referral sources, if applicable | ☐ | ☐ | ☐ | ☐ |
| 3. Clinic procedures for handling participant emergencies | | | | |
| a. Medical | ☐ | ☐ | ☐ | ☐ |
| b. Psychiatric | ☐ | ☐ | ☐ | ☐ |
| c. Breaking the blind, if applicable | ☐ | ☐ | ☐ | ☐ |
| I. Are procedures for working with other Support Services (e.g., radiology, pathology, pharmacy) in place? | ☐ | ☐ | ☐ | ☐ |
| 10. Investigator and staff responsibilities: | | | | |
| 1. Information flow among study staff documented and understood | ☐ | ☐ | | ☐ |
| 2. CTP management has been informed about the upcoming study and their role | ☐ | ☐ | | ☐ |
| 3. Non-protocol CTP staff (e.g., receptionist, telephone operator, etc) have been informed of the study and instructed how to handle participants' calls and questions | ☐ | ☐ | | ☐ |
| 4. Procedures in place for assuring safety of RA and other study staff | ☐ | ☐ | | ☐ |
| D. Are monitoring procedures (requirements, frequency, and site contacts per protocol QA plan) understood? | ☐ | ☐ | | ☐ |
| E. Was the Site Visit Log available and signed? | ☐ | ☐ | | |
| **Comments:** | | | | |

| **III. Review of Informed Consent, HIPAA Procedures, and Enrollment Documentation** | **Yes** | **No** | **N/A** | **N/R** |
|---|---|---|---|---|
| A. Does the site have the most current IRB-approved Informed Consent(s) and HIPAA authorizations (if applicable) on file and ready for use? | ☐ | ☐ | | ☐ |
| B. Are informed consent and HIPAA procedures understood? | ☐ | ☐ | | ☐ |
| C. Are the screening procedures for this protocol understood by study staff? | ☐ | ☐ | ☐ | ☐ |

| **III. Review of Informed Consent, HIPAA Procedures, and Enrollment Documentation** | **Yes** | **No** | **N/A** | **N/R** |
|---|---|---|---|---|
| D. Was the Master Enrollment Log/Index for this protocol available? | ☐ | ☐ | ☐ | ☐ |
| E. Are storage plans adequate to assure confidentiality? | ☐ | ☐ | | ☐ |
| **Comments:** | | | | |

| **IV. Review of Study Drugs and Drug Accountability Records**<br><br>☐ **N/A- not a medication trial, and ancillary medications will not be used as part of the protocol; skip to next section.** | **Yes** | **No** | **N/A** | **N/R** |
|---|---|---|---|---|
| A. Has initial shipment of medications been received and properly stored in a secured area? | ☐ | ☐ | | ☐ |
| B. Are medications supplies adequate to begin study? | ☐ | ☐ | | ☐ |
| C. Is condition of medications appropriate for use (e.g., expiration date, physical condition of medication)? | ☐ | ☐ | | ☐ |
| D. Are copies of initial medication shipment records current and accurate/dated and signed? | ☐ | ☐ | | ☐ |
| E. Are all medication supplies accounted for by actual count? | ☐ | ☐ | | ☐ |
| F. Are procedures for drug dispensing and accountability records for study medications adequate and understood? | ☐ | ☐ | | ☐ |
| G. Are procedures for drug return by participants, reconciliation, retrieval or destruction, and reordering in place and understood? | ☐ | ☐ | | ☐ |
| H. Are procedures in place for maintaining or breaking the medication blind, if applicable? | ☐ | ☐ | ☐ | ☐ |
| I. Are State Drug Regulatory Certificates in place, if applicable? | ☐ | ☐ | ☐ | ☐ |
| **Comments:** | | | | |

| **V. Protocol Procedures and Compliance** | **Yes** | **No** | **N/A** | **N/R** |
|---|---|---|---|---|
| A. Are recruitment procedures in place and adequate per protocol? | ☐ | ☐ | ☐ | ☐ |
| B. Are screening procedures adequate per protocol? | ☐ | ☐ | ☐ | ☐ |
| C. Are inclusion/exclusion criteria understood? | ☐ | ☐ | ☐ | ☐ |

| V. Protocol Procedures and Compliance | Yes | No | N/A | N/R |
|---|---|---|---|---|
| D. Are randomization procedures understood? | ☐ | ☐ | ☐ | ☐ |
| E. Are plans for study intervention administration in place according to protocol? | ☐ | ☐ | ☐ | ☐ |
| F. Are procedures for maintaining the blind, if applicable, in place and understood? | ☐ | ☐ | ☐ | ☐ |
| G. Does the staff understand “missed visit” procedures per protocol? | ☐ | ☐ | ☐ | ☐ |
| H. All schedules of events/assessments understood? | ☐ | ☐ | | ☐ |
| I. Are tracking plans in place for follow-up visits, per protocol? | ☐ | ☐ | ☐ | ☐ |
| **Comments:** | | | | |

| VI. Adverse Events & Serious Adverse Events | Yes | No | N/A | N/R |
|---|---|---|---|---|
| A. Are Adverse Event reporting and tracking procedures, per protocol and local IRB requirements, understood? | ☐ | ☐ | ☐ | ☐ |
| B. Are definitions for Study-related AEs and SAEs understood? | ☐ | ☐ | ☐ | ☐ |
| C. Are all procedures for Serious Adverse Event reporting, tracking, and documentation in place and understood? | ☐ | ☐ | ☐ | ☐ |
| D. Are local IRB SAE reporting and documenting procedures understood? | ☐ | ☐ | ☐ | ☐ |
| E. Is staff aware that every SAE must have a corresponding AE CRF? | ☐ | ☐ | ☐ | ☐ |
| **Comments:** | | | | |

| VII. Case Report Forms/Source Documentation | Yes | No | N/A | N/R |
|---|---|---|---|---|
| A. Are current versions of CRFs available to begin screening/consenting (i.e., several participant binders are assembled, ready for use)? | ☐ | ☐ | ☐ | ☐ |
| B. Does the site have the most current version of the CRF completion instructions? | ☐ | ☐ | ☐ | ☐ |
| C. Are source documents defined? | ☐ | ☐ | ☐ | ☐ |
| D. Are CRF/data correction and submission procedures understood? | ☐ | ☐ | ☐ | ☐ |
| E. Are data query completion and submission procedures and timeliness understood? | ☐ | ☐ | ☐ | ☐ |
| **Comments:** | | | | |

| VIII. Protocol Violation(s) | Yes | No | N/A | N/R |
|---|---|---|---|---|
| A. Are protocol violation (PV) definition and procedures for documenting them understood? | ☐ | ☐ | | ☐ |
| B. Are users identified for the PV web-based tracking system, and CTN Staff ID #s recorded with the CTN PV system manager, if applicable? | ☐ | ☐ | ☐ | ☐ |
| C. Are regulations regarding reporting PVs to local IRB understood? | ☐ | ☐ | ☐ | ☐ |
| **Comments:** | | | | |

| IX. Local/Central Laboratory Procedures | Yes | No | N/A | N/R |
|---|---|---|---|---|
| A. Are local or central laboratory procedures in place (e.g., collection, handling, labeling, storage, disposal, and shipment of supplies and study samples)? | ☐ | ☐ | ☐ | ☐ |
| B. Are equipment and supplies for proper handling of laboratory samples available? | ☐ | ☐ | ☐ | ☐ |
| C. Are procedures in place and do research staff understand the protocol procedures for assessing and documenting clinical significance of laboratory data by medical personnel? | ☐ | ☐ | ☐ | ☐ |
| **Comments:** | | | | |

| X. Site Staff Training/Readiness Status | Yes | No | N/A | N/R |
|---|---|---|---|---|
| A. Is there adequate staff to perform all protocol procedures? | ☐ | ☐ | | ☐ |
| B. Have all CTP research staff satisfied the PTP 002 training requirements for this protocol? | ☐ | ☐ | | ☐ |
| **Comments:** | | | | |

| XI. Issues Identified | Date first Identified | Action Required (describe) | Resolved? If No, provide action and/or update. |
|---|---|---|---|
| | | | ☐ Yes ☐ No |

| **XI. Issues Identified** | Date first Identified | Action Required (describe) | Resolved? If No, provide action and/or update. |
|---|---|---|---|
| | | | ☐ Yes ☐ No |
| | | | ☐ Yes ☐ No |

Summary:

_____
_____
_____
_____
_____
_____
_____

**XIII. Is another site initiation visit planned?** ☐ Yes ☐ No

If yes, provide scheduled/planned date: _____ / _____ / _____

**XIV.** Date of NIDA contract monitor visit, if known: _____ / _____ / _____

List and attach to this report any supporting documents if needed:

☐ No Attachments

☐ _____ ☐ _____
☐ _____ ☐ _____

I certify that the above information is, to the best of my knowledge, correct and accurate.

Monitor's Name(s) _____
_____